Life Spine®

AUG 2 2 2006

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510(k) Summary of Safety and Effectiveness

510(k) Summary - ARX™ Spinal System

Submitted By:	Life Spine 2400 Hassell Road, Suite 370 Hoffman Estates, IL 60195 Telephone: 847-884-6117 Fax: 847-884-6118
510(k) Contact:	Erin Malloy Life Spine 2400 Hassell Road, Suite 370 Hoffman Estates, IL 60195
Date Prepared:	June 7, 2006
Trade Name:	ARX™ Spinal System
Common Name:	Appliance, Fixation, Spinal Interlaminal
Classification:	888.3070 Pedicle screw spinal system
Device Product Code:	MNH, CFR 888.3070, Class II MNI, CFR 888.3070, Class II
Predicate Device:	DePuy AcroMed™ Moss® Miami Spinal System Stryker Spine TRIO® Spinal Fixation System

Device Description:

The ARX™ Spinal System includes various types and sizes of single use implantable components. When assembled, the components create a rigid structure providing stabilization and promoting spinal fusion. The system is comprised of bone screws and rods. Class I surgical instruments are utilized for the installation of the implant.

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Intended Use of the Device:

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The ARX™ Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as a posterior spine thoracic/lumbar system, the ARX™ Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Material:

The ARX™ Top-Loading Thoracolumbar Spinal System is manufactured from medical grade titanium alloy described by ASTM F136.

Performance Data:

Biomechanical testing in accordance with ASTM F1717 was conducted to demonstrate substantial equivalency.

Substantial Equivalence:

The ARX™ Spinal System was shown to be substantially equivalent to previously cleared devices, the DePuy AcroMed™ Moss® Miami Spinal System and the Stryker Spine TRIO® Spinal Fixation System, in indications for use, design, function, and materials used.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Life Spine
% Ms. Erin Malloy
Project Engineer
2400 Hassell Road, Suite 370
Hoffman Estates, Illinois 60195

AUG 2 2 2006

Re: K061600
Trade/Device Name: ARX Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 7, 2006
Received: June 8, 2006

Dear Ms. Malloy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Life Spine®

K061600

Indications for Use

510(k) number (if known): _____

Device Name: ARX™ Spinal System

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The ARX™ Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities.

When used as a posterior spine thoracic/lumbar system, the ARX™ Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Prescription Use __x__ (Part 21 CFR 801 Subpart D) And/Or Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Barbara Bruch MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061600

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